MERIDIAN
MEDICAL TECHNOLOGIES
A Pfizer Company

Meridian Medical Technologies, Inc.
1945 Craig Road
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December 28, 2017

Miguel A. Hernández
Director, Compliance Branch
US Food and Drug Administration
8050 Marshall Drive, Suite 205
Lenexa, KS 66214

RE: Meridian Medical Technologies, Inc. / FEI Number: 1950222
(b) (4) Enhancement Plan
September 01, 2017 – November 30, 2017 Update

Dear Mr. Hernández:

In the December 17, 2014 response to the Form FDA 483 issued November 25, 2014, Meridian Medical Technologies, Inc. ("MMT") included a commitment to provide FDA with a comprehensive description of actions being taken to enhance the capability of the (b) (4) (b) (4) filling equipment prior to resuming production of auto-injectors (the "(b) (4) Enhancement Plan" or "Plan"). As reported out in the previous quarterly report, MMT decided to replace the (b) (4) filler with new contemporary filling equipment.

The "Plan" was submitted on February 28, 2015. MMT also committed to submitting quarterly updates, the first of which was provided on June 12, 2015. MMT hereby provides the eleventh quarterly update to cover the time period from September 01, 2017 – November 30, 2017.

Background

Following an FDA inspection that concluded in April 2013, MMT committed to implementing corrective actions for the production of products that relied exclusively on manual visual inspection for the detection of missing drug. This commitment applied to products manufactured on the (b) (4) filler and also for products manufactured on the (b) (4) filling line, which used manual visual inspection for detection of missing drug. MMT also identified opportunities to enhance the process for products produced on the (b) (4) filling line, which used a (b) (4) and manual visual inspection to detect missing drug.

As previously reported, MMT's focus had been on ATNAA/DuoDote manufacturing process enhancements using the (b) (4), which was directed by MMT's key client. In May 2015, MMT received direction from its client to resume work on the (b) (4) enhancement activities after the aseptic site maintenance spring shutdown concluded. (b) (4) (b) (4) (b) (4)

As outlined in the previous quarterly report, MMT decided to procure a new (b) (4) filler replacing the legacy (b) (4) filler. The new (b) (4) filler was designed to meet contemporary manufacturing standards such as (b) (4) that could not be implemented on the (b) (4) filler.

The process qualification and product validation in support of the (b) (4) NDA submission will be conducted on the new (b) (4) filler using glass cartridges from a new supplier ((b) (4) (b) (4) that in initial studies showed improved qualities over the original glass cartridges.

The current timeline covering the procurement and qualification activities that are in progress for the new (b) (4) filler is provided as **Exhibit 1**.

New (b) (4) filler Plan Update

Following MMT's decision to pursue the process qualification and product validation in support of the submission of the (b) (4) NDA on the new (b) (4) filler, user requirements were provided to the supplier. The supplier (b) (4) finalized the initial fabrication of the new filler ((b) (4) filler') in late November. Factory Acceptance Testing will commence in December of this year with onsite delivery expected in January 2018. The installation qualification including Site Acceptance Testing and Installation and Operation Qualification will be initiated in February 2018. Updates on these activities will be provided in future quarterly updates.

The re-design and initial construction phase of the aseptic suite to accommodate the new (b) (4) filler' was successfully completed during the regular 2017 fall shutdown of the aseptic core.

As outlined in the previous quarterly report, MMT procured and will use glass cartridges from an alternate supplier ((b) (4)) who uses a different manufacturing process compared to the original glass supplier that should result in improved glass cartridges for future qualification activities on the (b) (4) filler'. MMT plans to conduct accelerated and long-term stability studies using the (b) (4) with units generated on the (b) (4) filler' during PQ later in 2018. Updates on these additional studies will be provided in future quarterly updates.

In addition, MMT is engaging an independent Third Party Subject Matter Expert (3rd Party SME) to conduct a review of the (b) (4) Design History File (DHF) against Combination products regulations 21 CFR 4.4(b)(1). Results from this independent review are expected in March 2018.

Projected milestones for the procurement and qualification actions for (b) (4) on the new (b) (4) filler in progress, based on input from MMT's customer, product priorities, and access to the aseptic core is provided as **Exhibit 1**. This timeline may require further adjustment based on additional findings and necessary corrective actions.

In consultation and alignment with MMT's clients, the activities for (b) (4) have been put on hold until qualification of (b) (4) is complete. The timeline for (b) (4) (b) (4) will be reinstated once the qualification activities for (b) (4) commence.

AtroPen-style auto-injector Enhancement Plan Update

As reported in previous quarterly updates for the AtroPen-style auto-injector products that were produced on the (b) (4) MMT has identified (b) (4) as an alternate material to the current (b) (4) material used for the AtroPen-style cartridge. The alternate material is intended to address (b) (4) issues that have been observed in the AtroPen and Morphine auto-injectors during stability.

MMT is working with the (b) (4) cartridge supplier on additional (b) (4) (b) (4)

In addition, MMT's engineering team is working on adjustments to the commercial AtroPen (b) (4) (b) (4) (b) (4)

Updates on these activities will be provided in future quarterly reports.

Based on the updated general evaluation of the (b) (4) filling equipment, MMT decided that the process qualification and product validation for the AtroPen-style products will be conducted on the new filler that MMT plans to procure in the future.

The updated timeline that also takes into consideration input from MMT's customer, product priorities, and access to aseptic core is provided as **Exhibit 2** outlining the projected milestone dates. This timeline may require further adjustment based on additional findings and necessary corrective actions.

MMT's next quarterly update on the Plan will be submitted by March 31, 2018 (for the three month period ending February 28, 2018). In the interim, please feel free to contact us with any questions or input.

Sincerely,

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